

K 071976

SUMMARY OF SAFETY AND EFFECTIVENESS

1. GENERAL INFORMATION

Page 1 of 3

1.1 Submitter and Owner of the 510(k)

Yves Arboy, President
VECTEC
Bioparc
03270 Hauterive
FRANCE
Establishment Registration: Pending

SEP - 6 2007

1.2 Official Correspondent

Diane Mandell Horwitz, Ph.D., RAC
THE WEINBERG GROUP INC.
1220 19th Street N.W., Suite 300
Washington, D.C. 20036
Telephone: 703.242.0027
Facsimile: 703.242.0027
Electronic mail: dianehorwitz@gmail.com

1.3 Date of Preparation

July 11, 2007

2. NAME OF THE DEVICES

2.1 Trade/Proprietary Names

VECTEC Disposable Trocars and Laparoscopic Accessories

2.2 Classification Information

Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Regulation:	21 CFR § 878.4400
Class:	II
Product Code:	GEI, electrosurgical, cutting and coagulation and accessories
Panel:	General and Plastic Surgery

SUMMARY OF SAFETY AND EFFECTIVENESS (Continued)**3. PREDICATE DEVICES**

Trocars	MTP Disposable Trocars	MTP Medical Technical Promotion GMBH (manufactured by VECTEC)	K994066
Scissors	Applied Laparoscopic Disposable Monopolar Scissor	Applied Medical Resources Corporation	K062169
Forceps and Dissectors	Disposable Re-New Forceps	Microline Pentax, Inc.	K981389
Hook	"Re-New" Laparoscopic Instruments (includes hook configuration)	Microline Pentax, Inc.	K962119

4. DESCRIPTION OF THE DEVICES

The VECTEC Disposable Trocars and Laparoscopic Accessories can be used in a variety of procedures (general, vascular, gynecological and thoracic surgical procedures) to cut, dissect, manipulate, and/or cauterize various tissues. Trocars are sterile, single-use devices that allow visualization of body cavities and use of the laparoscopic accessories. The accessory devices are disposable, single use, individually packaged devices that are composed of biocompatible materials. Scissors, forceps, and dissectors have a handle attached to an insulated shaft with different tips, which allows the shaft and tip to rotate. They include a male cautery connector when attached to standard monopolar cautery cables and their generators. All devices are sterilized using a traditional, validated ethylene oxide procedure per EN 550:1994 to a SAL of 10^{-6} and with acceptable residual EO levels per ISO 0993-7:1995.

5. INDICATIONS FOR USE AND INTENDED USE

The VECTEC Disposable Trocar and Laparoscopic Accessories are single-use, sterile devices intended to provide access to and visualization of body cavities, organs, and canals and to cut, dissect, manipulate, and/or cauterize various tissues during endoscopic/laparoscopic, general, vascular, gynecological and thoracic surgical procedures. Accessories include scissors, forceps, dissectors and a hook.

6. SUBSTANTIAL EQUIVALENCE

The VECTEC Trocars (the subject of this application) and the predicate trocars (K994066) are both manufactured by VECTEC and are identical; thus, they are substantially equivalent.

Substantial equivalence of the scissors, forceps, dissectors, and hook is demonstrated by the similarity in Intended Use of instruments to their predicate. The devices are similar in characteristics to the predicate devices, and both are composed of biocompatible materials. The energy source that is used with the VECTEC accessories, monopolar electrosurgical energy, is the same as used for the predicate devices. Comparison of

SUMMARY OF SAFETY AND EFFECTIVENESS (Continued)

technological characteristics and bench electrosurgical device performance testing has confirmed that the VECTEC Disposable Trocars and Laparoscopic Accessories are substantially equivalent to the predicate devices.

7. PERFORMANCE TESTING

VECTEC laparoscopic accessories met the dielectric withstand testing requirements of ANSI/AAMI HF-18:2001.

8. CONCLUSIONS

Based on the technical testing and dimensional information and intended use information provided, the VECTEC Disposable Trocars and Laparoscopic Accessories have been shown to be substantially equivalent to the predicate devices listed above.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

VECTEC
% The Weinberg Group, Inc.
Diane Mandell Horwitz, Ph.D., RAC
Regulatory Consultant
1220 Nineteenth Street, Northwest
Suite 300
Washington, District of Columbia 20036-2400

SEP - 6 2007

Re: K071976
Trade/Device Name: VECTEC Disposable Trocar and Laparoscopic Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 17, 2007
Received: July 17, 2007

Dear Dr. Horwitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

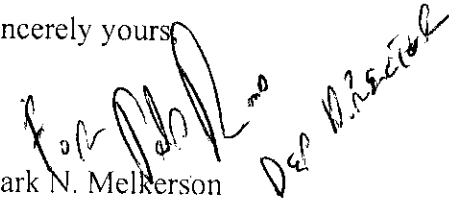
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


Mark N. Melkersen
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K071976

Device Name: VECTEC Disposable Trocar and Laparoscopic Accessories

Indications for Use:

The VECTEC Disposable Trocar and Laparoscopic Accessories are single-use, sterile devices intended to provide access to and visualization of body cavities, organs, and canals and to cut, dissect, manipulate, and/or cauterize various tissues during endoscopic/laparoscopic, general, vascular, gynecological and thoracic surgical procedures. Accessories include scissors, forceps, dissectors and a hook.

Prescription Use X AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K071976